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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,988	12/09/2003	Suresh K. Arya	4239-67517	9402

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EXAMINER

HILL, MYRON G

ART UNIT PAPER NUMBER

1648

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/731,988	Applicant(s) ARYA, SURESH K.	
	Examiner Myron G. Hill	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/1/05, and 11/21/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 7-9, 11-15, 17, 21 and 43-50 is/are pending in the application.
- 4a) Of the above claim(s) 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 7-9, 11-15, 17, 21, 43-46, and 48-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/22/05</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
|--|--|

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on 21 November 2005 is acknowledged. The traversal is on the ground(s) that the inventions are have been searched from the independent claim and that the election should t least be a species election. This is not found persuasive because each sequence requires a separate search and applicant has not shown that all the sequences are species.

The requirement is still deemed proper and is therefore made FINAL.

Claim 47 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 7-9, 11-15, 17, 21, 43-46, and 48-50 are under consideration.

Priority

The Office acknowledges the amendment that updates the first line of the specification to include the current status of the parent application.

Information Disclosure Statement

A signed and initialed copy of the IDS filed 22 June, 2005 is enclosed.

Art Unit: 1648

Rejections Withdrawn

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 7-9, 11-15, 17, 21, and 43-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has amended the claims and the rejection is withdrawn.

Claims 7, 8, 10, 14, 15, and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants arguments were persuasive and the rejection is withdrawn.

Claims 7, 8, 11, 14, 15, 17, 21, and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SD36 (deleted regions as recited in the first specific construct listed in claim 9), does not reasonably provide enablement for all deletions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The declaration of has Kafri has been considered. The rejection is withdrawn.

Art Unit: 1648

Claim Rejections - 35 USC § 103

Claims 7-15, 17, 21, and 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poeschla *et al.* (from IDS, JV 1998) and MacCann *et al.* (JV 1997, from IDS).

The rejection is withdrawn on the showing from the declaration of Arya that removes Poeschla *et al.* by showing prior invention.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 7, 11, and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by Arya *et al.* (Human Gene Therapy 1998 Vol. 9, pages 1371-1380).

The invention is drawn to HIV-2 packaging vectors with deletions upstream and downstream of the major splice donor site and the splice donor site is still functional.

Arya *et al.* teach the same vector, see figure I.

Thus, Arya *et al.* anticipate the claimed invention.

Claim Rejections - 35 USC § 103

Claims 7, 8, 11-13, 15, 17, 21, 43, 48, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arya *et al.* as applied to claims 7, 11, and 15 above, and further in view Verma *et al.* (US Pat 6013516 from IDS).

The invention is drawn to HIV-2 packaging vectors with deletions upstream and downstream of the major splice donor site and the splice donor site is still functional as well as variations to make other viral vectors.

Arya *et al.* teach functional deletion of HIV-2 packaging signal by deletion upstream and downstream of the SD site.

Verma *et al.* teach a vector system (Figure I).

One of ordinary skill in the art at the time of invention would have known that the deletion of packaging signals were needed to construct viral vectors and would have known the potential benefits of using HIV-2 as a viral vector. One of ordinary skill in the art at the time of invention would have known the various systems developed for HIV-1 and would have been able to use them for HIV-2 knowing what packaging sequences were needed.

Thus, it would have been *prima facie* obvious to use the HIV-2 packaging vector with mutations upstream and downstream of the SD site as taught by Arya *et al.* for use in vector systems with the expectation of success.

Art Unit: 1648

Claims 7, 8, 11-13, 15, 17, 21, 43, 48, and 50 are rejected under 35 U.S.C.

103(a) as being unpatentable over McCann *et al.* and Verma *et al.* (US Pat 6013516)

The invention is drawn to HIV-2 packaging vectors with deletions upstream and downstream of the major splice donor site and the splice donor site is still functional as well as variations to make other viral vectors.

McCann *et al.* teach functional deletion of HIV-2 packaging signal by deletions upstream and downstream of the SD site (Figure I).

Verma *et al.* teach a vector system (Figure I).

One of ordinary skill in the art at the time of invention would have been motivated to combine the mutations of McCann *et al.* (Figure I) to create a vector with deletions both upstream and downstream knowing that mutations upstream and down stream of the SD site were involved in packaging with the expectation of reducing packaging even further. One of ordinary skill in the art at the time of invention would have known that the obliteration of packaging signals were needed to construct viral vectors. One of ordinary skill in the art at the time of invention would have known the various systems developed for HIV-1 and would have been able to use them for HIV-2 knowing what packaging sequences were needed.

Thus, it would have been *prima facie* obvious to make an HIV-2 packaging vector with mutations upstream and downstream of the SD site for use in vector systems with the expectation of success.

Art Unit: 1648

Conclusion

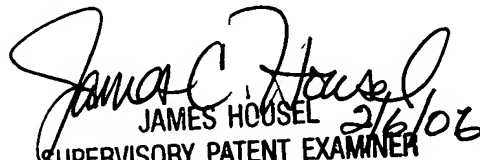
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Myron G. Hill
Patent Examiner
3 February 2006


JAMES HOUSEL 2/6/06
SUPERVISORY PATENT EXAMINER
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